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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/225,233	01/04/1999	KEITH HENRY STOCKMAN CAMPBELL	SP-01-US-DIV-1	2711
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EXAMINER				
CROUCH, DEBORAH				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/225,233

Applicant(s)

CAMPBELL ET AL.

Examiner

Deborah Crouch, Ph.D.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2008 and 09 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 155-159 and 164 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 155-159 and 164 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 08/802,282.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-854/3)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Intervenor Patent Application
- 6) ☐ Other: _____

A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on May 9, 2008 has been entered. The amendment filed March 30, 2008 has been entered. Claims 155-159 and 164 are pending. The declaration by Irina A. Polejaeva, Ph.D. filed March 30, 2008 has been considered but is not persuasive for the reasons given below.

Applicant has previously filed proper terminal disclaimers regarding U.S. Patents 6,137,276; 6,252,133 and 6,525,243. The present claims are still seen as obvious over these patents. However, an obviousness-type double patenting rejection was not made since terminal disclaimers had been filed and approved.

Applicant's amendment to the claims has overcome the statutory type (35 U.S.C. 101) double patenting rejection made in the Examiner's Answer mailed September 6, 2006.

Applicant's amendment to the claims has overcome the rejection made under 35 U.S.C. 112, first paragraph in the Examiner's Answer mailed September 6, 2006

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 155-159 and 164 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent 6,548,741; claims 1-20 of U.S. Patent 7,232,938; claims 1-22 of U.S. Patent No. 7,304,204; claims 1-18 of U.S. Patent 7,307,198; claims 1-8 of U.S. Patent 7,321,076; claims 1-23 of U.S. Patent 7,326,824; claims 1-54 claims 1-20 of U.S. Patent 7,326,825; claims 1-37 of U.S. Patent No. 7,332,648; claims 1-21 of U.S. Patent 7,355,094; and claims 1-32 of U.S. Patent No. 7,361,804. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed cloned cattle, sheep,

pigs and goats are a species produced by the methods claimed in the above mentioned patents.

Present claims 155-159 and 164 are directed to cloned cattle, sheep, pigs and goats made by a general method of nuclear transfer. The present specification discloses donor cells as being diploid, differentiated, somatic cells in the G0 or G1 phase of the cell cycle.

Claims 1-10 of U.S. Patent 6,548,741; claims 1-20 of U.S. Patent 7,232,938; claims 1-22 of U.S. Patent No. 7,304,204; claims 1-18 of U.S. Patent 7,307,198; claims 1-8 of U.S. Patent 7,321,076; claims 1-23 of U.S. Patent 7,326,824; claims 1-54 claims 1-20 of U.S. Patent 7,326,825; claims 1-37 of U.S. Patent No. 7,332,648; claims 1-21 of U.S. Patent 7,355,094; and claims 1-32 of U.S. Patent No. 7,361,804 are directed to methods of producing cloned nonhuman mammals, ungulates, cattle, cows, bovines, sheep, ovines, pigs and goats using donor cells in the G0 or G1 phase of the cell cycle.

Thus, at the time of the instant invention, it would have been obvious to the ordinary artisan to arrive at the presently claimed cloned cattle, sheep, pigs and goats given the methods claimed in any of the above mentioned patents.

Claims 155-159 and 164 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27-34 and 43-50 in U.S. application serial no. 11/543,786 and claims 19-26 and 35-42 in U.S. application serial no. 11/544,038. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either

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anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed cloned cattle, sheep, pigs and goats are a species produced by the methods claimed in the above mentioned patents.

Present claims 155-159 and 164 are directed to cloned cattle, sheep, pigs and goats made by a general method of nuclear transfer. The present specification discloses donor cells as being diploid, differentiated, somatic cells in the G0 or G1 phase of the cell cycle.

Claims 27-34 and 43-50 in 11/543,786 and claims 19-26 and 35-42 in 11/544,038 are directed to ungulate reconstituted embryos comprising a quiescent ungulate cell or a diploid ungulate differentiated cell. The embryos are disclosed as being transferred to a female for term development.

Thus at the time of the instant invention it would have been obvious to the ordinary artisan to produce the cloned cattle, sheep, pigs and goats of the present claims given the reconstituted embryos of the claims in '786 or '038.

Claims 155-159 and 164 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-27, 30-36, 40-56, 63, 83, 84 and 97-102 of copending Application No. 11/068,903. Although the

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conflicting claims are not identical, they are not patentably distinct from each other because the claims of '903 are generic to the present claims.

Present claims 155-159 and 164 are directed to a live-born clone of a pre-existing, non-embryonic donor cattle, sheep, pigs and goats produced by nuclear transfer. The present specification discloses donor cells as being diploid, differentiated, somatic cells in the quiescent, G0 or G1 phase of the cell cycle.

Claims 19-27, 30-36, 40-56, 63, 83, 84 and 97-102 of '903 are directed to methods of preparing a pig embryo, a cloned pig, a nonprimate mammalian embryo or nonprimate mammal comprising inserting the nucleus of a cultured diploid differentiated pig or nonprimate mammalian nuclear donor cell into an unactivated, enucleated metaphase II-arrested pig or nonprimate mammalian oocyte, activating the resulting embryo and developing the activated embryo to term.

Thus at the time of the instant invention, it would have been obvious to the ordinary artisan to produce the cloned cattle, sheep, goats and pigs of present claims given the methods of claims 19-27, 30-36, 40-56, 63, 83, 84 and 97-102 of '903.

These are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

35 U.S.C. 101 reads as follows :

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 155-159 and 164 remain rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter for reasons set forth in the

Examiner's Answer mailed September 11, 2006 and the BPAI Decision, mailed January 30, 2008. Claims 155-159 and 164 are drawn to a live born clone of a pre-existing, non-embryonic, donor mammal, wherein the mammal is selected from cattle, sheep, pigs and goats. However, the claimed mammals do not sufficiently distinguish over pre-existing cattle, sheep, pigs and goats. Neither the claims nor the specification point out any structure or phenotype that separates the cloned mammals from the pre-existing mammal. The method of making the mammals does not imbue any new or novel characteristic to the cloned mammals nor does the method imbue a new use to the mammals claimed. Further, the claims clearly state that the clone is a copy of a pre-existing mammal. Hence, the mammal as claimed is indistinguishable from the mammal as found in nature. Thus, the cloned nonhuman mammals of the claims is not seen as being "new" as required by 35 U.S.C. § 101.

It is well known and accepted that patentability is precluded for certain subject matter, products of nature, natural phenomenon, being one of them. The claimed cloned nonhuman mammals were, as disclosed in the specification, indeed, produced by a method that has the hand of man associated with it. However, the question raised under 35 U.S.C. § 101 relates to the patentability of subject matter that occurs in nature, is a copy of a product of nature, but the copy was created by the hand of man. Does the hand of man extend through the method to the product?

The actuality is, applicant developed a method whereby an embryo can be made by an in vitro method, and the embryo is transferred to a surrogate female nonhuman mammal. The surrogate female nonhuman mammal actually "makes" a cloned

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nonhuman mammal from applicant's in vitro produced embryo. By virtue of "employing" the naturally occurring female to produce the clone, a copy or replica of a prior existing mammal, the resultant mammal is a product of nature. In this regard, a cattle, sheep, pig or goat produced by IVF is a product of nature, even though the embryo was made in vitro. There are no structural differences between a cattle, sheep, pig or goat produced by mating, IVF or cloning, at least none are disclosed in specification or recognized in the art.

Since there is no alteration of the cloned nonhuman mammals claimed versus nonhuman mammals produced by other means, cloned a cattle, sheep, pig or goat cannot be distinguished from its IVF or mating produced counterpart. Without a distinction, each cloned cattle, sheep, pig or goat is a product of nature. As detailed below, applicant's evidence and arguments are not persuasive.

To reiterate, the cloned nonhuman mammals of the claim have not been described by the specification or the art as having any distinguishing effect by the hand of man method of making them. Thus, while applicant has a method that exhibits clearly the hand of man, it is not clear than the mammal products of the method exhibit the hand of man. Applicant, it would appear has invention a new method to produce a product of nature, similar to the IVF situation. There is no case law, other decisional law or policy that directs the patentability of fundamentally wild-type cattle, sheep, pigs and goats produced by in vitro methods.

With regard to the BPAI instituted rejection, applicant argues "new" in 35 U.S.C. § 101 is not ignored. Applicant argues the cloned cattle, sheep, pigs and goats are

"new" because it does not exist in nature, but is made by man. Applicant continues in stating, in view of the BPAI's anticipation analysis, the clones are patentable because none of the references disclose exactly what is claimed. Applicant argues anticipation is not shown by prior art disclosure which only "substantially" is the same as the claimed invention. Applicant argues the identical invention must be shown in the prior art in as complete detail as is contained in the claim. Applicant argues any difference precludes anticipation as established by legal precedent. Applicant argues differences between the claimed clones and their parents have been set forth in the declaration of David Wells previously filed, and the concurrently filed declaration by Irina A. Polejaeva, Ph.D. at parag. 92-110. These arguments are not persuasive.

35 U.S.C. § 101 states "Whoever invents or discovers any *new* and useful process, machine, manufacture, or composition of matter, or any *new* and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." What permeates the prosecution of this application is how to distinguish the cloned cattle, sheep, pig or goat, *new* according to applicant, from cattle, sheep, pig or goat known in nature. There is no way to distinguish them, or at least none have been set forth. The cloned cattle, sheep, pig and goat look the same, behave the same, have the same chromosome number, same proteins, same physiology, same biochemistry, and they are used for same purposes. Their *newness* is not apparent. Applicant argues the clones are *new* in a 101 sense because of the method of making them, but applicant never states what the *new* is. A new way of making a product does not give the product "new" features necessarily. The method could provide new features

to the product, but in the present prosecution no new features, characteristics, structure have been provided.

While it can be agreed upon, the clone and the nucleus donor cattle, sheep, pig or goat will have differences. Some differences will be caused by epigenetic differences, others by genetic differences. This is true for all animals. However, the differences have not been stated, nor has the effect of the differences been shown to make the clone "new." A clone could have crooked horn, the donor, a curved horn. A clone could have a white star on its muzzle; the donor have an all black muzzle. Yes, these are differences, but do they make the clone new, or do they make the clone statutory subject matter. The clone doesn't have a new use by having a crooked horn or a white star on its muzzle. It still functions the same as the donor mammal. How the clone is new and statutory is not clear from the specification, the art or the prosecution history. Applicant is attempting to establish newness by alluding to uncontrollable events that have no effect on the use of the clone. Given applicant's line of reasoning, a goat with a white coat is patentably distinct from a goat with a black coat. Coat color, marking and horns are not affected by the cloning method. The specification does not identify any step in the cloning method as regulating any structural characteristic of the clone. Thus, the characteristics the BPAI labeled as trivial are the differences that have no effect on the substance of the cloned cattle, sheep, pig or goat over the nuclear donor cattle, sheep, pig or goat.

Declarant Polejaeva states (parag. 94-110, pages 17-19) her opinion as to the differences between a clone and the nuclear donor mammal. Declarant states: parag.

94. Based on my experience cloning mammals, Applicant's clone is not made by nature; parag. 95. Based on my experience cloning mammals, Applicant's clone can only be made by human intervention; parag. 96. Based on my experience cloning mammals, Applicant's clone is not an exact copy of its donor mammal; parag. 97. Based on my experience in mammalian reproduction, environmental factors would generate differences between Applicant's clone and its donor mammal; parag. 98. Based on my experience cloning mammals, Applicant's clone could not exist before it was made; parag. 99. Based on my experience cloning mammals, Applicant's clone occupies different space and time than its donor mammal, and is a time-delayed, inexact copy of its donor mammal. The clone contains the same genetic complement as its donor mammal, but is not an exact copy due to environmental differences during development; parag. 100. The ability of Applicant's clone to exist at a time later than its donor mammal, but have the same genetic complement, is a markedly different characteristic from any mammal found in nature; parag. 101. Based on my experience in mammalian reproduction, no mammal found in nature is a time-delayed copy of either of its parents; parag. 102. Based on my experience cloning mammals, Applicant's clone provides an alternative, time-delayed source of nuclear genomic material of its donor mammal; parag. 103. Based on my experience cloning mammals, this feature of Applicant's clone does not depend on the continued existence of the donor mammal; parag. 104. Consequently, Applicant's clone can provide an alternative source of nuclear genomic material of its donor mammal, even if the donor mammal is dead; parag. 105. The time delay of Applicant's clone allows the preservation of the genomic

material of a particular mammal beyond the normal lifespan of that mammal; parag. 106. Normally, when a mammal dies, its particular genomic composition is lost. Its progeny only contain one-half of each of its two parents' genomic material. The genomic material of one parent is inextricably scrambled together with the other parent's genomic material to create the progeny; parag. 107. Based on my experience cloning mammals, Applicant's clone avoids this permanent loss of a particular genomic composition; parag. 108. Thus, Applicant's clone provides the potential for the continuation of a particular genomic composition in a way that never occurs in nature; parag. 109. Based on my experience cloning mammals, this cannot be considered a trivial difference as compared to a clone's donor mammal, which does not have this potential; and parag. 110. Moreover, Applicant's clone requires two animals, namely, a pre-existing, non-embryonic, donor mammal and a clone of that donor mammal. Based on my experience in mammalian reproduction, nature never makes such a pair of mammals. Declarant's statements are not persuasive.

Each of declarant's statements is an outcome provided by the method of nuclear transfer disclosed in the specification. There is no evidence that being a time-delayed clone of a mammal provides any feature to indicate the hand of man. Further, there is no evidence on record, in the specification or by declarant of any structural feature to a clone that indicates the hand of man. What is the aspect of the method that removes the cloned nonhuman mammal from the realm of non-statutory? Applicant seems to have invented a new method of producing a non-statutory class of invention.

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In the art rejections below, the rejections have been made under 35 U.S.C. § 102/103. The phrase "live-born clone of a ... mammal" imbues the method by which the clone was made, nuclear transfer.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skills in the art to which said subject matter pertains. patentability shall not be negated by the manner in which the invention was made.

Claims 155, 156 and 164 (cattle) remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sims et al. (1993) Proceed. Natl. Acad. Sci. 90, 6143-6147 for reasons set forth in the Examiner's Answer mailed September 11, 2006.

Sims teaches cloned bovines (page 6146, col. 1, parag. 2, lines 6-11).

Claims 155, 157 and 164 (sheep) remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over McLaughlin et al (1990) Reproduction Fertil. Develop. 2, 619-622 for reasons set forth in the Examiner's Answer mailed September 11, 2006.

1). McLaughlin teaches cloned sheep (page 620, parag. 2-5, and page 621, parag. 1).

Claims 155, 158 and 164 (pigs) remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Prather et al (1989) Biology of Reproduction 41, 414-418 for reasons set forth in the Examiner's Answer mailed September 11, 2006.

Prather teaches a cloned pig (page 415, col.1, parag. 1 to page 416, line 8, and page 416, col. 2, lines 8-10

Claims 155, 159 and 164 (goats) remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yong et al (1991) Theriogenology 35, page 299 for reasons set forth in the Examiner's Answer mailed September 11, 2006.

Yong teaches cloned goats by nuclear transfer of the reconstituted goat embryos (parag. 2 and Table).

Applicant argues the cited prior art does not teach the exact cloned cattle, sheep, pig and goat claimed. Applicant argues the cited art (Sims, McLaughlin, Prather and Yong) teach clones produced using an embryonic cell as the nuclear donor. The clone of the art is not, as argued by applicant, a clone of a pre-existing, non-embryonic donor mammal. Applicant argues the Declarant states the embryos used in the cited art as nuclear donors were generated by sexual reproduction and are not identical to either parent. Applicant argues the donor embryos were destroyed during the embryonic cloning procedures. Applicant argues the embryonic donor cells of the prior art were never non-embryonic. Further, Applicant argues Declarant states the cloned mammals

in the cited prior art have two parents, whereas the claimed clones have one parent. Applicant argues Declarant states the clones in the cited prior art would have been mixture of the genetic complement of their two parents. Applicant argues Declarant states the claimed cattle, sheep, pig and goat are time-delayed, inexact copies of a non-embryonic mammal. Applicant argues Declarant states the claimed mammals require only the donor mammal and the clone, whereas are requires a sperm, an egg to make the embryo, and then the clone. These arguments are not persuasive.

Neither applicant nor declarant provide for a method to distinguish between the cattle, sheep, pig or goat of the cited prior art and those of the present claims. In other words, if a herd of cattle contained both cloned and "natural" cattle, sheep, pigs or goats, how would one distinguish between them? In a side-by-side comparison, what are the features that distinguish between the clone and those mammals of the prior art? How does one identify a time-delayed mammal? Further, how does one determine if a particular nonhuman mammal was a clone, that is had a single "parent" or if the mammal had to two parents? How does one know if a particular nonhuman mammal contained a mix of two genetic complements, if the mammal was produced sexually or my sperm fertilization of an ovum? Applicant has argued these as distinguishing features but there is no means provided to determine such features. In particular, there is no means provided to determine between the claimed nonhuman mammals and those in the cited prior art.

If the clone and the mammal are of the same species, then they inherently have the same genetic complement, the same genes. A clone contains the mixture of two

genetic complements, even if it is a mixing of grandparental genomes. Applicant now states the clones claimed are not exact copies of the nuclear donor mammals, but does not state how they are not exact. Declarant states environmental factors generate differences between the clone and the nuclear donor (parag. 97), but declarant does not define the environmental factors and their effects. Declarant states the clone and the donor have the same genetic complement but environmental differences make the clone not an exact copy (parag. 99), but there is no explanation or evidence provided. Further, what are the environmental issues affecting the claimed clones and are these affects present in the cattle, sheep, goat and pig of the cited prior art? Neither applicant nor declarant addresses any particular distinguishing features.

Neither applicant nor declarant defines "genetic complement." The Online Medical Dictionary states a genetic complement is "The set of chromosomes contained within any one particular cell." From this definition, a mammal does not necessarily have the same genetic complement in each of its cell. Therefore, the clones claimed may or may not have the same cattle genetic complement, the same sheep genetic complement, the same pig genetic complement or the same goat genetic complement in each of its cells. The clone can contain cells with a chromosomal make up different from that of the nuclear donor. It is important to realize during cell division, DNA replication is not 100% faithful, meaning silent or not silent mutations may arise. Considering a complete cattle, sheep, pig or goat, there can be many such mutations, which would make the absolute DNA sequence of each chromosome in each cell potentially different. Importantly, there is no evidence the "genetic complement" renders a

distinguishing feature. If the clone does not have the exact same genetic complement in each cell as the donor mammal, the genetic complement offers no bases to distinguish the clone from the art.

Applicant has not described any distinguishing feature between the claimed clones and the cattle, sheep, pigs or goats in the cited prior art. Again, how does the ordinary artisan tell the difference between the sheep clone claimed, and the sheep of McLaughlin, for example. How do you distinguish from mammal produced by mating from a clone, or a mammal produced by IVF from a clone? From reading the specification, there are no such differences between the cloned mammals and other mammals. If cattle are examined in the field, how does the ordinary artisan know which cattle an inexact copy of a prior existing cattle?

Applicant argues Declarant states the method of embryo cloning precludes the co-existence of the clone and embryo donor because the embryo donor was destroyed during production of the clone. Applicant argues Declarant states only when the donor cell is non-embryonic can the clone and the donor co-exist. Applicant argues Declarant states the claims cannot be obvious because prior to their invention the generation of a live born clone of a pre-existing, non-embryonic, donor mammal would have been expected to be impossible. These arguments are not persuasive.

There is no requirement in the claims that the donor mammal and the clone exist at the same time. "Pre-existing" means the donor existed before the donor mammal but does not infer anything about the status of the donor at the present time. The donor could be dead or alive. The method of generating a clone, it is agreed, was unexpected

at the time of filing. However, the method is for making an art recognized, old product. The product is not patentable because the method does not provide a patentable distinction to the old product.

Finally, the references cited under 35 U.S.C. § 102(b)/103 rejections, meet the all the limitations of the claims. Since cloning does not affect the structure of the cloned cattle, sheep, pig or goat, there is no patentable distinction between the cattle, sheep, pig and goats of the claims and those in the art. Applicant should point to structural differences provided by the method of cloning. Without such, there is no patentable difference between the two.

New Rejections under 35 U.S.C. § 102/103

The rejections below establish the claimed cloned cattle, sheep, goat and pig are not patentably distinct from cattle sheep, goat and pig produced by sperm fertilization of an ovum.

Claims 155, 156 and 164 (cattle) are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Zinn (1993) J. Animal Science, Vol. 71, pp. 3-10.

Zinn teaches cross-bred steers, cattle (page 3, col. 2, parag. 1, line1 to page 4, col. 1, line 3). As the presently claimed cloned cattle do not exhibit a novel structural or functional difference from those described in Zinn, Zinn anticipates the claimed invention. In the alternative, the claimed cattle is obvious over Zinn because there is no structural or functional difference between the claimed cattle and the bovines of Zinn. In

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a side-by-side comparison, the ordinary artisan would not differentiation between the cattle claimed and those of Zinn. The specification does not disclose any structural or physical features that would distinguish between the cattle claimed and those known in the art at the time of filing. Applicant should note those physical and structural differences that distinguish the claimed cattle from those of Zinn. The specification does not provide for such, and no such differences are observed in the cattle are noted in the specification. Thus, Zinn either anticipates or makes obvious the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 155, 157 and 164 (sheep) are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Aldrich et al. (1993) J. Animal Sci., Vol. 71, pp. 158-163.

Aldrich teaches young sheep or lambs (page 158, col. 2, parag. 2, lines 1-3). As the presently claimed cloned sheep do not exhibit a novel structural or functional difference from those described in Aldrich, Aldrich anticipates the claimed invention. In the alternative, the claimed sheep is obvious over Aldrich because there is no structural or functional difference between the claimed sheep and the sheep of Aldrich. In a side-

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by-side comparison, the ordinary artisan would not differentiation between the sheep claimed and those of Aldrich. The specification does not disclose any structural or physical features that would distinguish between the sheep claimed and those known in the art at the time of filing. Applicant should note those physical and structural differences that distinguish the claimed sheep from those of Aldrich. Thus, Aldrich either anticipates or makes obvious the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 155, 158 and 164 (pigs) are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Matte et al. (1993) J. Animal Sci., Vol. 71, 151-157.

Matte teaches female pigs or gilts (page 151, col. 2, parag. 1, lines 1-2). As the presently claimed cloned pigs do not exhibit a novel structural or functional difference from the pigs described in Matte, Matte anticipates the claimed invention. In the alternative, the claimed pig is obvious over Matte because there is no perceived structural or functional difference between the claimed pigs and the pig of Matte. In a side-by-side comparison, the ordinary artisan would not differentiation between the pigs

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claimed and those of Matte. The specification does not disclose any structural or physical features that would distinguish between the pigs claimed and those known in the art at the time of filing. Applicant should note those physical and structural differences that distinguish the claimed pigs from those of Matte. Thus, Matte either anticipates or makes obvious the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 155, 159 and 164 (goats) are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ortega-Reyes et al. (1993) J. Animal Sci., Vol. 71, pp. 3380-383.

Ortega-Reyes teaches goats (page 380, col. 2, parag. 2, lines 1-2). As the presently claimed cloned goat does not exhibit a novel structural or functional difference from the goat described in Ortega-Reyes, Ortega-Reyes anticipates the claimed invention. In the alternative, the claimed goat is obvious over Ortega-Reyes because there is no perceived structural or functional difference between the claimed goat and the goat of Ortega-Reyes. In a side-by-side comparison, the ordinary artisan would not differentiation between the goat claimed and that of Ortega-Reyes. The specification

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does not disclose any structural or physical features that would distinguish between the goat claimed and those known in the art at the time of filing. Applicant should note those physical and structural differences that distinguish the claimed goat from that of Ortega-Reyes. Thus, Ortega-Reyes either anticipates or makes obvious the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is (571)272-0727. The examiner can normally be reached on M-Fri, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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/Deborah Crouch, Ph.D./
Primary Examiner, Art Unit 1632

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